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09/777,018	02/05/2001	Roger N. Hastings	5236-000215	5479

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EXAMINER	
BRANDT, ADAM CURTIS	
ART UNIT	**PAPER NUMBER**
3771	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/777,018	HASTINGS ET AL.	
	Examiner	Art Unit	
	Adam Brandt	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 34-37, 39 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (US 5681260).

Ueda et al. disclose a device comprising a catheter 8 having a proximal and a distal end and a lumen therebetween (Figure 28). A catheter is defined as "a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway." (dictionary.com). Therefore, the catheter 8 of Ueda et al. reads on this definition. Ueda et al. continues to disclose a support structure 22/94/140 in the lumen adjacent the distal end. Ueda et al. also discloses one or more optical conduits 16/25 in the catheter 8, each having a distal end supported by the support structure 22/94/140 and one or more magnetic members (19/82/20/95) disposed in the distal end of the catheter 8. In addition, the distal end of the catheter 8 is oriented by one or more magnetic members (19/82/20/95) that align relative to the direction of an externally applied magnetic field from magnetic generator 11/31 (Abstract). Lastly, Ueda et al. teach one or more optical conduit 16/25 in the distal end is inherently capable of being rotated within a support structure 22/94/140. The support structure as stated can be broadly interpreted as section 140 or 22 within a tubular device. It is considered inherent that the

optical conduits can be rotated within the catheter device manually since the conduits are loosely inserted within the support structure allowing the conduit to be rotatable. In addition, articulation frames 22 that can be broadly interpreted as a support structure are connected rotatably with each other; therefore, the optical conduits 16/25 that fit adjacent to these support structures would inherently be capable of rotation as well (column 8, lines 31-41).

As for claim 35, the magnet members (19/82/20/95) disposed in the distal end of the catheter that orient the distal end to align relative to an applied magnetic field 11/31, whereby the distal end is oriented by changing the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field (Abstract).

In regards to claims 36 and 37, Ueda et al. teach a support structure 140 comprising one or more magnetic members 142 (Figure 25). Ueda et al. continue to disclose a support structure comprising a sheath 84/85 (Figure 11).

As for claim 39, Ueda et al. disclose one or more magnetic members 142 disposed in the distal end of the catheter 8, whereby the distal end is oriented by the one or more magnetic members that align relative to the direction of an externally applied magnetic field 11/31. In addition, the one or more magnet members 142 are positioned within the catheter 8 and are inherently capable of being rotatable within the catheter since the magnet is manually inserted into channel 140, therefore, the magnet is capable of being manually rotated in any direction.

As for claim 44, Ueda et al. discloses in figure 27 the device of claim 39 wherein at least one optical conduit comprises an optical fiber having a beveled distal end facing generally radially outwardly for imaging the Bessel in which the device is located (see column 18, ln. 9-10).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Conlan et al. (US 5904147) and further in view of Goldenberg (US 4830460).

Ueda et al. disclose a vivisecting forceps (column 12, line 17) or the like except doesn't explicitly teach a device comprising a laser ablation tool. However, Conlan et al. disclose a catheter device including an optical conduit 42 and being magnetically oriented by an external magnetic field as shown in Figure 7. Conlan et al. teach the tip of the catheter as having an ablation instrument (column 10, lines 25-31). Goldenberg further teaches a guidance system with an ultraviolet laser ablation tool at the catheter distal end (column 3, lines 20-21). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Ueda et al. by replacing the forceps with a laser ablation tool of Conlan et al. and Goldenberg in order to remove specific blockage in a user's body.

As for claim 42, Ueda et al. teach a support structure 94/140 comprising a passage for a guide wire. Goldenberg discloses a similar support structure in a sleeve 72 that explicitly teaches a passage for a guidewire 70 (column 13, lines 65-68). Therefore, it would have been obvious for a person having ordinary skill in the art at the time of the invention to advance a guidewire through this passage to ensure an optical fiber remains in alignment.

5. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Conlan et al.

Ueda et al. discloses in column 8, lines 1-24, an optical imaging system for acquiring an image of the interior circumference of a vessel in which the device is located and also discloses in column 7, lines 53-67, an optical conduit used to emit light on the insertable tip. Ueda fails to disclose a laser energy source for conducting ablating laser energy to the distal end of the device. Conlan teaches the tip of the catheter as having an ablation instrument (column 10, lines 25-31) that is supplied with energy via an optical fiber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the second optical conduit of Ueda to deliver laser energy to the ablating device of Conlan in order to minimize the effects of hemorrhaging by visual inspection via imaging system located in the first optical conduit.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 34-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. US 5681260 in view of Ueda et al.

The sheath in claims 7, 18, and 19 reads on a support structure of claim 1 of the instant application. An energy source in claims 1, 18, and 19 can be broadly interpreted as an optical conduit or vice versa. Lastly, the magnetically active element in claims 1 and 18-20 reads on the magnetic members in claim 1 of the instant application. As for the optical conduit or energy source as being rotatable, Ueda et al. teach one or more optical conduit 16/25 in the distal end as being inherently capable of rotation within a support structure 22/94/140. The support structure as stated can be broadly interpreted as section 140 or 22 within a tubular device. It is considered inherent that the optical conduits can be rotated within the catheter device manually since the conduits are loosely inserted within the support structure allowing the conduit to be rotatable. In addition, articulation frames 22 that can be broadly interpreted as a support structure are connected rotatably with each other; therefore, the optical conduits 16/25 that fit adjacent to these support structures would inherently be capable of rotation as well (column 8, lines 31-41). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of the claims of '026 with the optical conduit being rotatable in order to position an optical conduit at a desired position before or during insertion.

8. Claims 38 and 40-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. US 5681260 and Ueda et al. in view of Conlan et al., and further in view of Goldenberg.

Ueda et al. disclose a vivisecting forceps (column 12, line 17) or the like except doesn't explicitly teach a device comprising a laser ablation tool. However, Conlan et al. disclose a catheter device including a optical conduit 42 and being magnetically oriented by an external magnetic field as shown in Figure 7. Conlan et al. teach the tip of the catheter as having an ablation instrument (column 10, lines 25-31). Goldenberg further teaches a guidance system with an ultraviolet laser ablation tool at the catheter distal end (column 3, lines 20-21). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention of the claims of '026 and Ueda et al. by replacing the forceps with a laser ablation tool of Conlan et al. and Goldenberg in order to remove specific blockage in a user's body.

Response to Arguments

9. Applicant's arguments filed 8/03/2006 with respect to claims 34-43 have been fully considered but they are not persuasive.

In response to the Applicants arguments of claims34, 35, and 39:

The Applicant argues that Ueda does not disclose a catheter device having magnetic members (19/82/20/95) that align relative to the direction of an externally applied magnetic field from a magnetic field generator (11/31/61). The Applicant further states that Ueda discloses a tip that is attracted by a magnetic force, which is moved towards a magnetic force generating part (31).

The Examiner notes that a magnetic force is a product of a magnetic field. Therefore, every magnetic field inherently has magnetic forces associated with it. Additionally, it is inherent that a magnet will align with the field by way of the force. Since the invention of Ueda discloses a tip that is attracted by a magnetic force which is generated at a remote location, it does in fact meet the claim limitation.

The Examiner fails to see how the example provided by the Applicant in the last paragraph of page 5 of the remarks relates to the argument. Ueda discloses a tip this movable in relation to the postion of a magnet which the Examiner supposes is analogous to the Applicant's example of "a magnet held close above a compass causes the compass needle to be attracted up towards the magnet". The Examiner understands the Applicants example as it applies to a magnet that is held above a conventional compass that lies flat on a table. The needle of the compass tries to escape its horizontal plane of movement in order to point towards to the magnet. In other words, the needle has some positive angle of elevation from the horizontal plane because the needle is trying to point towards the magnet. The needle of the compass, which has its vertical movement restricted by a securing means (such as a pin) will thus align itself with the polarity of the magnet.

The Applicant's second example is of "a magnet rotated above a compass that causes the compass needle to rotate and align with the direction of the magnetic field of the rotating magnet". The example provided by the Applicant is interpreted by the Examiner as a conventional compass laying flat on a table so that the needle can move in the horizontal plane. A conventional 2-pole magnet is placed over top of the compass. When rotated the needle of the compass rotates with the magnets position so that the needle is aligned with the orientation of the

magnet. The Examiner fails to how these examples clarify the arguments set forth in the Applicant's preceding paragraphs.

The Applicant recites that the disclosure teaches that a magnetic field is used to align the tip relative to the direction of the field and therefore, unlike Ueda, the claimed magnet members may be aligned in a desired direction other than towards the magnet by changing the magnetic field's direction. The Examiner notes that in paragraph 43, line 16-17, the Applicant discloses that magnetic force is used to align the tip. Magnetic forces are used to align the tip relative to the magnetic field so it will move in the proper direction. Ueda discloses a tip that utilizes magnetic forces to direct its movement. The Examiner believes that Ueda discloses the limitation set forth in the Applicants claims.

In response to the Applicants arguments of claims 38, and 40-43:

The arguments have been responded to above.

In response to the Applicants arguments towards the Double Patenting Rejection:

The arguments have been responded to above.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Brandt

Adam Brandt
Examiner
Art Unit 3771

ACB

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11/8/06